REMARKS/ARGUMENTS

In response to the Office Action of June 17, 2005, Applicant has herein amended Claim 1 to recite that the material of the microneedles is substantially sugars that dissolve within the human body, which was the subject matter of original, now cancelled, Claim 11. As all of the other original claims depend from Claim 1, this Amendment is applicable to these other claims as well. New Claims 31 and 32 also depend from Claim 1. New Claim 31 adds that the sugar material is substantially maltose. New Claim 32 adds the configuration of the microneedles with relatively thick inner portions and relatively thick outer portions with constricted intermediate portions therebetween to facilitate separation of the outer portions from the inner portions with the outer portions remaining in the skin. New Claim 33 includes the subject matter of original Claim 1, without the presently amended language, and adds the needle configuration subject matter of new Claim 32. New Claim 34 contains the subject matter of original Claim 1 without the present amended subject matter and recites the microcontainers containing the functional substance and being contained within the microneedles for delivery into the skin. New Claim 35 depends from Claim 34 and adds that the microcontainers are disposed in barbed tips of the microneedles for separation of the barbed tips with the microcontainers from the remainder of the microneedles for retention in the skin.

The Office Action rejected Claims 1-5, 7-10, 14-16 and 19-30 as being anticipated under 35 USC § 102(b) by Park et al. U.S. Patent Publication No. 2002/0082543 A1. As Claim 1 has now been amended to include the "substantially sugars" limitation of Claim 11, which was not rejected as being anticipated by Park et al., the rejection of Claims 1-5, 7-10, 14-16 and 19-30 as anticipated by Park et al. is no longer apt and should be withdrawn.

The subject matter of original Claim 11, which is now incorporated in Claim 1, was rejected in the Office Action as being obvious under 35 USC § 103(a) on the basis of Park et al. in

view of D'Ussel U.S. Patent Publication No. 2004/0010237 A1 with the assertion in the Office Action that D'Ussel describes a needle made substantially of sugars that dissolve within the human body, referring to page 1, paragraph 14.

D'Ussel does not disclose or suggest a needle made of a material that is substantially sugars, as recited in Claim 1. Rather, D'Ussel discloses, in paragraph 0012, that the needle is made "generally of metal such as aluminum." It is only a sharp tip at the end of the metal needle that is disclosed in D'Ussel as being made of "sugar, salt or any similar product." This tip is said in paragraph 0016 to be formed by a drop of material deposited on the rounded end of the metal needle. This drop of sugar forms a closure for the end of the metal needle to close the duct in the needle to retain the liquid substance to be injected until the needle is inserted, at which time the sharp tip dissolves in body fluids so that the duct is opened and the substance can be injected (paragraph 0019).

D'Ussel does not disclose microneedles. It discloses a needle, not a plurality of needles, and the needles would clearly be standard size needles. Furthermore, there is no disclosure or suggestion, rather the contrary is evident, of producing sharp tips on microneedles by immersing microneedles in a hot solution of sugar.

The attached Declaration of Yoshikazu Tobinaga, whose expertise is established by the summary of his professional background attached to his Declaration as Exhibit A, verifies that one skilled in the art recognizes that D'Ussel discloses a standard size needle, not microneedles, and only the tip is formed of a sugar or salt, which tip is formed by immersing the needle in hot sugar or salt. D'Ussel teaches adding a tip of sugar to an existing metal structure, not forming needles of sugar. The Declaration goes on to state that sterilization disclosed by D'Ussel would disintegrate needles, if they were made of sugar. Thus, the disclosure of D'Ussel is inoperative such that one of ordinary skill in the art would not be taught by D'Ussel to make microneedles

of sugar, but would rather disregard D'Ussel as inoperative when considered in relation to microneedles.

For the foregoing reasons, it is clear that Claim 1 patentably defines over Park et al. and D'Ussel and that no combination of Park and D'Ussel would render the subject matter of Claim 1 obvious.

As original Claims 2-10 and Claims 12-30 and new Claims 31 and 32 depend from Claim 1, they are patentable for the same reasons as stated above for Claim 1.

In addition to being allowable on the basis of depending from Claim 1, Claim 12 further recites that the microneedles are restricted intermediate there ends to facilitate breaking off the portions of the needles beyond the narrow portions to leave these portions in the skin. The Office Action rejects Claim 12 on the basis of Park in view of Arias U.S. Patent Publication No. 2002/0133129 A1. However, Arias, which is relied on by the Examiner as disclosing microneedles constricted intermediate there ends with reference to Figure 15L, does not disclose a restriction intermediate the ends of microneedles. Rather, Arias, in Figure 15L discloses needles that progressively become smaller from the base to the tip. The tips are the portions of the Arias needles that are restricted in relation to the other portions. There is no restriction intermediate the ends in Arias, rather the restriction progresses to the end and there is no portion beyond the narrowest portion that could possibly break off and remain in the skin. Further, there is no teaching or suggestion otherwise in the Arias reference. In addition, paragraph 0171 of Arias discloses that the needles may be metallic, which obviously would be hazardous if broken off and left in the skin, contrary to the purpose of dissolvable sugar portions being left in the skin according to the present invention.

Claim 13 recites a structure that facilitates separation of the outer portions of the microneedles from the inner portions with the outer portions remaining in the skin. There is no

structure in the Arias reference that results in outer portions remaining in the skin. Rather, as pointed out above, it would be hazardous if the outer portion of the Arias needle remained in the skin.

Claim 14 is rejected as being anticipated by Park, with reference to Figure 5 of Park. However, Claim 14 recites that the tips of the microneedles are knife-shaped. The microneedles shown in Figure 5 of Park are not knife-shaped. They appear to be conical. Therefore, Park does not anticipate the subject matter of Claim 14.

Claim 15 recites that the applicators have microcontainers containing functional substance and being contained within the microneedles. The Office Action rejects Claim 15 on the basis of Park, with reference to Figure 3. However, Figure 3 of Park illustrates a layered microneedle. In paragraph 0023 of Park, the microneedle is disclosed as being formed of multiple layers, not microcontainers. There is no teaching or suggestion in Park of the use of microcontainers contained in microneedles. Therefore, Park does not anticipate the subject matter of Claim 15.

Claim 16 depends from Claim 15 and is not anticipated by Park for the same reasons. Further, Claim 16 includes microneedles with barbed tips in which the microcontainers are disposed for separation with the barbed tips from the remainder of the microneedles. The Office Action rejects Claim 16 on the basis of Figure 3 of Park. However, not only is there no microcontainer in Figure 3 of Park, but there are no barbed tips. Rather, the tips of the microneedles of Figure 3 of Park are simply conical continuations of the remainder of the microneedles. Therefore, Park does not anticipate the subject matter of Claim 16.

New Claim 31 recites that the material of the microneedles is substantially maltose. Therefore, Claim 31 is allowable for the same reasons as Claim 1 and further because maltose is not disclosed or suggested in any of the cited prior art.

New Claim 32 depends from Claim 1 and adds that the microneedles are formed with relatively thick inner and outer portions with restricted intermediate portions to facilitate separation of the outer portions. Therefore, Claim 32 is allowable for the same reasons as Claim 1 and further because there is no disclosure or suggestion in the prior cited patents of relatively thick inner and outer portions with constricted intermediate portions that facilitate separation of the outer portions for remaining in the skin.

New Claim 33 contains the subject matter of original Claim 1, without the "substantially sugar" term added to Claim 1 as now amended, but Claim 33 recites the same recitation as Claim 32 of relatively thick inner and outer portions and constricted intermediate portions. As mentioned above, this configuration is not disclosed or suggested in the cited prior art.

New Claim 34 also recites the subject matter of original Claim 1 without the "substantially sugars" term added in the current amendment of Claim 1, but does contain the microcontainers feature of Claim 15 and is distinguishable from the prior art for that reasons.

New Claim 35 depends from Claim 34 and adds the feature of the microcontainers disposed in barbed tips of the microneedles as recited in Claim 16. Therefore, Claim 35 is patentable over the cited prior art for the same reasons as discussed above with regard to this feature in Claim 16.

In view of the foregoing, it is respectfully submitted that all of the pending claims as amended, Claims 1-10 and 12-35 patentably distinguish over the cited prior art and are allowable. Reconsideration and allowance are respectfully requested.

Respectfully submitted,

Dalbert U. Shefte
U.S. Reg. No. 18,174
Kennedy Covington Lobdell & Hickman, L.L.P.
Hearst Tower, 47th Floor
214 North Tryon Street
Charlotte, NC 28202
Attorney for Applicant
(Phone) 704-331-5790
(Fax) 704-353-3690